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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/571,184

07/17/2006

David Morton

478.1077

9629

23280 7590 10/22/2010  
Davidson, Davidson & Kappel, LLC  
485 7th Avenue  
14th Floor  
New York, NY 10018

EXAMINER

OLSON, ERIC

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

10/22/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/571,184	MORTON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ERIC S. OLSON	1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's information disclosure statement submitted August 11, 2010.
2. ☒ The allowed claim(s) is/are 1-3,6-8,10,11,13-25 and 30-50.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date <u>8/11/2010</u></li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date ____.</li> <li>7. <input type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other ____.</li> </ol> |
|---|--|

/Eric S Olson/  
Primary Examiner, Art Unit 1623

### **Detailed Action**

This office action is a supplemental office action in response to applicant's information disclosure statement submitted August 11, 2010. This application is a national stage application of PCT/GB04/03932, filed September 15, 2004, which claims priority to foreign applications GB 0321611.6, filed September 15, 2003, and GB 0327723.3, filed November 28, 2003.

Claims 1-3, 6-8, 10, 11, 13-25, and 30-50 are pending in this application.

Claims 1-3, 6-8, 10, 11, 13-25, and 30-50 as amended are examined on the merits herein.

### **Reasons for Allowance**

Applicant's information disclosure statement, submitted August 11, 2010, has been fully considered and not found to be the basis for any new grounds of rejection against the claims as previously allowed in the notice of allowance submitted July 28, 2010.

Specifically the information disclosure statement includes a copy of a European office action in a related foreign application and a copy of the PCT international publication WO00/33811 cited in the European office action. This reference WO00/33811 discloses aerosol formulations comprising leucine and an active agent, and further suggests using heparin as an active agent. However, the reference does not disclose specifically using 2% or more by weight of leucine in a formulation with heparin as the active ingredient. Furthermore, those examples provided for other active

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agents show that formulations using 1% leucine have a respirable fraction equal to or greater than those having a greater amount of leucine. By contrast, as discussed in the previous notice of allowance on July 28, 2010, the instant specification clearly demonstrates that for combinations of leucine and heparin, using 2% or greater w/w of leucine produces an unexpected increase in the respirable fraction. Therefore, Applicant has demonstrated unexpected results sufficient to overcome any *prima facie* case of obviousness over the cited document WO00/33811.

Accordingly, Applicant's information disclosure statement submitted August 11, 2010, is not the basis for any grounds of rejection against the previously allowed claims, and the claims therefore remain allowable.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/  
Primary Examiner, Art Unit 1623  
10/19/2010